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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

JENEANE BAQUE, individually and on behalf of all others similarly situated,

Plaintiffs,

vs.

MEDTRONIC, INC., a corporation,

Defendant.

Case No. 3:07-cv-5352-WHA

DEFENDANT MEDTRONIC, INC.'S ANSWER TO PLAINTIFF'S COMPLAINT AND REQUEST FOR JURY TRIAL

Compl. Filed: October 19, 2007

Honorable William H. Alsup

Defendant Medtronic, Inc. ("Medtronic"), by and through undersigned counsel, hereby answers Plaintiff's Complaint for Damages and Equitable Relief and Class Action and Demand for Jury Trial ("Complaint"), asserts its affirmative defenses, submits its jury demand, and in support thereof states and alleges the following:

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PRELIMINARY STATEMENT

To the extent that the title and headings inserted by Plaintiff at various points in the Complaint are intended to make or infer claims or allegations against Medtronic, they are, unless specifically admitted, denied.

PARTIES

1. Medtronic is without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 1 of the Complaint.

2. Medtronic admits that it is a corporation existing under the laws of the State of Minnesota, with its principal place of business at 710 Medtronic Parkway, Minneapolis, Minnesota, 55432. Medtronic admits that it develops technology to treat conditions such as heart disease and other illnesses. Medtronic admits that it or one of its affiliates manufactures medical devices and sells them worldwide and denies that it manufactures medical devices throughout the United States. Medtronic admits that its Cardiac Rhythm Disease Management Division ("CRDM") develops, researches, advertises, promotes, markets and sells implantable cardiac defibrillators ("ICDs") and leads, some of which leads are marketed under the trade name "Sprint Fidelis." Medtronic admits that CRDM's operations are principally conducted out of its facilities in Minneapolis, Minnesota , at its current address of 8200 Coral Sea Street N.E., Mounds View, Minnesota 55112. Medtronic denies the remaining allegations of Paragraph 2 of the Complaint.

INTRODUCTION

3. Medtronic admits that it or one of its affiliates designs, researches, develops, manufactures, tests, markets, advertises, promotes, distributes, and sells products that treat cardiac arrhythmias, heart failure, and coronary and peripheral vascular disease. Medtronic admits that an

arrhythmia is an irregular cardiac rhythm. Certain types of cardiac arrhythmias can, under certain circumstances, lead to decreased cardiac output and serious injury or death. Medtronic admits that it is a global leader in medical technology, alleviating pain, restoring health and extending life for millions of people around the world. Medtronic denies the remaining allegations of Paragraph 3 of the Complaint.

4. Medtronic admits the first sentence of Paragraph 4. Medtronic admits that devices designed to detect and treat abnormally fast and irregular heart rhythms and to provide pacing for improper heart rhythms are available from Medtronic, including ICDs. Medtronic admits that ICDs, depending on the model and the particular implementation and programming of the device, can have four functions, sensing/pacing, cardioversion, defibrillation, and long term support pacing. Medtronic admits that a pacemaker is used primarily to correct slow heart rates. Medtronic admits that, among other things, some ICDs detect and provide therapy for both fast and slow heart rates. Medtronic denies the remaining allegations of Paragraph 4 of the Complaint.

5. Medtronic admits the allegations of Paragraph 5 of the Complaint.

6. Medtronic admits that typically, wires called leads are inserted through a major vein and placed against the muscle on the inside of the heart through either active or passive fixation. Medtronic admits that electrodes that can sense the heart's rhythm are built into the leads and positioned in the heart, where they can monitor the heartbeat and deliver particular therapies as programmed by a physician. Medtronic denies the remaining allegations of Paragraph 6 of the Complaint.

7. Medtronic is without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 7 relating to Plaintiff Baque and purported class members. Medtronic admits that certain untreated cardiac arrhythmias can result in the loss of consciousness or

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death. Except as thus stated, Medtronic denies the remaining allegations of Paragraph 7 of the Complaint.

8. Medtronic admits that ICDs and leads can save lives. Medtronic further admits that under certain circumstances, untreated cardiac arrhythmias can result in the loss of consciousness, injury, and/or death. Except as thus stated, Medtronic denies the remaining allegations of Paragraph 8 of the Complaint.

THE SPRINT FIDELIS LEADS

9. To the extent that Paragraph 9 purports to be a characterization of Plaintiff's own Complaint, no response is required. To the extent a response is required, Medtronic refers to its answers to the substantive allegations of the Complaint contained herein. Further answering, Medtronic admits that it or one of its affiliates marketed Sprint Fidelis leads under model numbers 6949, 6948, 6931 and 6930. Except as thus stated, Medtronic denies the remaining allegations of Paragraph 9 of the Complaint and denies that this action is a proper class action.

10. Medtronic admits that it or one of its affiliates researched, developed, manufactured, marketed, sold and distributed Sprint Fidelis leads and Sprint Fidelis leads are used in connection with ICDs. Medtronic denies any remaining allegations of Paragraph 10 of the Complaint.

11. Medtronic admits that many ICDs use two or three leads. Medtronic further admits that Sprint Fidelis leads are smaller high-voltage leads. Medtronic is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 11.

12. Medtronic admits that in 2001 it marketed the Sprint Quattro Secure defibrillator lead, model 6947 and denies the remaining allegations in Paragraph 12.

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13. Medtronic admits that in 2004 it introduced and marketed the Sprint Fidelis lead. Except as thus stated, Medtronic denies the remaining allegations of Paragraph 13 of the Complaint.

14. To the extent that the allegations of Paragraph 14 rely upon public documents, the documents speak for themselves and Medtronic refers to them for the full content of such documents. To the extent that such allegations vary from any of the statements contained in the public documents, Medtronic denies those allegations.

15. To the extent that the allegations of Paragraph 15 rely upon public documents, the documents speak for themselves and Medtronic refers to them for the full content of such documents. To the extent that such allegations vary from any of the statements contained in the public documents, Medtronic denies those allegations.

16. Medtronic admits that the Sprint Fidelis leads were approved for sale by the United States Food and Drug Administration ("FDA"), but denies that such approval took place in September 2004. Medtronic admits that Sprint Fidelis leads have been implanted in over 160,000 patients worldwide and, further answering, states that, as of October 15, 2007, Sprint Fidelis leads had been implanted in approximately 268,000 patients worldwide.

17. Medtronic admits the allegations of Paragraph 17.

18. Medtronic admits that Models 6949 and 6948 have two defibrillation coils (one for the superior vena cava and one for the right ventricle; whereas Models 6930 and 6931 have one defibrillation coil for the right ventricle. Medtronic admits that as of January 2007 in the United States, an estimated 144,300 model 6949 Sprint Fidelis leads, 7500 model 6948 leads, 5400 model 6931 leads, and 200 model 6930 leads had been implanted. Medtronic denies the remaining allegations of Paragraph 18.

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THE DEFECTS IN THE SPRINT FIDELIS LEADS

19. Medtronic denies the allegations of Paragraph 19 of the Complaint.

20. Medtronic is without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 20. Further answering, to the extent that the allegations of Paragraph 20 rely upon public documents, the documents speak for themselves and Medtronic refers to them for the full content of such documents. To the extent that such allegations vary from any of the statements contained in the public documents, Medtronic denies those allegations.

21. Medtronic is without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 21. Further answering, to the extent that the allegations of Paragraph 21 rely upon public documents, the documents speak for themselves and Medtronic refers to them for the full content of such documents. To the extent that such allegations vary from any of the statements contained in the public documents, Medtronic denies those allegations.

22. Medtronic is without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 22. Further answering, to the extent that the allegations of Paragraph 22 rely upon public documents, the documents speak for themselves and Medtronic refers to them for the full content of such documents. To the extent that such allegations vary from any of the statements contained in the public documents, Medtronic denies those allegations.

23. Medtronic is without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 23. To the extent that the allegations of Paragraph 23 rely upon public documents, the documents speak for themselves and Medtronic refers to them for the full content of such documents. To the extent that such allegations vary from any of the statements contained in the public documents, Medtronic denies those allegations.

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24. Medtronic is without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 24 relating to Plaintiff. Medtronic denies the remaining allegations of Paragraph 24 of the Complaint. To the extent that the Paragraph purports to be a request for relief, Medtronic denies that it is liable to Plaintiff for any of the relief requested.

25. To the extent that the allegations of Paragraph 25 rely upon public documents, the documents speak for themselves and Medtronic refers to them for the full content of such documents. To the extent that such allegations vary from any of the statements or information contained in the public documents, Medtronic denies those allegations and denies any remaining allegations of Paragraph 25.

26. Medtronic denies that it concluded its leads were defective. To the extent that the allegations of Paragraph 26 rely upon public documents, the documents speak for themselves and Medtronic refers to them for the full content of such documents. To the extent that such allegations vary from any of the statements contained in the public documents, Medtronic denies those allegations and denies any remaining allegations of Paragraph 26.

27. To the extent that the allegations of Paragraph 27 rely upon public documents, the documents speak for themselves and Medtronic refers to them for the full content of such documents. To the extent that such allegations vary from any of the statements contained in the public documents, Medtronic denies those allegations. Medtronic denies any remaining allegations in Paragraph 27 of the Complaint.

28. Medtronic admits that it issued a communication to physicians on March 21, 2007. That document speaks for itself. To the extent that such allegations of Paragraph 28 vary from any of the statements contained in the document, Medtronic denies those allegations. Except as thus stated, Medtronic denies the remaining allegations of Paragraph 28 of the Complaint.

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29. Medtronic admits that on October 15, 2007, it voluntarily suspended worldwide distribution of the Sprint Fidelis leads. Medtronic admits that it stated that based on then current information, it had identified five patient deaths in which a Sprint Fidelis lead fracture may have been a possible or likely contributing factor. Medtronic refers to the full content of its October 15, 2007 communication (and appendices) to physicians and denies any allegations contained in Paragraph 29 that vary from the statements contained in that communication and denies any remaining allegations of Paragraph 29.

30. Medtronic denies the allegations of Paragraph 30 of the Complaint.

31. Medtronic denies the allegations of Paragraph 31, except to the extent that Medtronic admits that some patients may in some circumstances be dependent on ICDs and leads to maintain an appropriate heart rhythm, and therefore, adequate cardiac output. Medtronic further admits that in some cases under some circumstances leads that have failed may not prevent the consequences of the arrhythmia. Except as thus stated, Medtronic denies the remaining allegations of Paragraph 31 of the Complaint.

32. Paragraph 32 states a legal conclusion to which no response is required. To the extent a response is required, Medtronic denies the allegations of Paragraph 32 of the Complaint.

33. Paragraph 33 states a legal conclusion to which no response is required. To the extent a response is required, Medtronic denies the allegations of Paragraph 33 of the Complaint.

SUMMARY OF ALLEGATIONS

34. Medtronic admits that it, or one of its affiliates, researched, developed, manufactured, marketed, promoted, advertised and sold Sprint Fidelis leads. Except as thus stated, Medtronic denies the remaining allegations of Paragraph 34 of the Complaint.

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35. Paragraph 35 states a legal conclusion to which no response is required. To the extent a response is required, Medtronic denies the allegations of Paragraph 35 of the Complaint.

36. Paragraph 36 states a legal conclusion to which no response is required. To the extent a response is required, Medtronic denies the allegations of Paragraph 36 of the Complaint.

37. Paragraph 37 states a legal conclusion to which no response is required. To the extent a response is required, Medtronic denies the allegations of Paragraph 37 of the Complaint.

38. Medtronic admits that over 129,000 Sprint Fidelis leads are currently active in patients residing in the United States and in other countries, and denies any remaining allegations of Paragraph 38 of the Complaint.

39. Paragraph 39 states a legal conclusion to which no response is required. To the extent a response is required, Medtronic denies the allegations of Paragraph 39 of the Complaint.

JURISDICTION AND VENUE

40. Paragraph 40 states a legal conclusion to which no response is required. To the extent a response is required, Medtronic denies the allegations of Paragraph 40 of the Complaint.

41. Paragraph 41 states a legal conclusion to which no response is required. To the extent a response is required, Medtronic denies the allegations of Paragraph 41 of the Complaint.

42. Paragraph 42 states a legal conclusion to which no response is required. To the extent a response is required, Medtronic denies the allegations of Paragraph 42 of the Complaint.

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43. Paragraph 43 states a legal conclusion to which no response is required. To the extent a response is required, Medtronic denies the allegations of Paragraph 43 of the Complaint.

44. Paragraph 44 states a legal conclusion to which no response is required. To the extent a response is required, Medtronic denies the allegations of Paragraph 44 of the Complaint.

CLASS ACTION ALLEGATIONS

45. To the extent that Paragraph 45 of the Complaint purports to define a class of individuals that Plaintiff seeks to represent, no response is necessary. To the extent a response is required, Medtronic denies that any such grouping of individuals represents an appropriate class for purposes of this proceeding.

46. Medtronic is without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 46.

47. Paragraph 47 states a legal conclusion to which no response is required. To the extent a response is required, Medtronic denies the allegations of Paragraph 47 of the Complaint.

48. Paragraph 48 states a legal conclusion to which no response is required. To the extent a response is required, Medtronic is without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 48.

49. Paragraph 49 states a legal conclusion to which no response is required. To the extent a response is required, Medtronic is without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 49.

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50. Paragraph 50 states a legal conclusion to which no response is required. To the extent a response is required, Medtronic denies the allegations of Paragraph 50 of the Complaint.

51. Paragraph 51 states a legal conclusion to which no response is required. To the extent a response is required, Medtronic denies the allegations of Paragraph 51 of the Complaint.

ALLEGATIONS

52. Medtronic admits that it, or one of its affiliates, designed, manufactured, marketed, promoted, sold and distributed Sprint Fidelis lead models 6949, 6948, 6931 and 6930. Except as thus stated, Medtronic denies the remaining allegations of Paragraph 52 of the Complaint. Medtronic specifically denies that any of the aforementioned lead models are defective.

53. Medtronic admits that the Sprint Fidelis leads were approved for sale by the FDA, but denies that such approval took place in September 2004.

54. Medtronic denies the allegations of Paragraph 54 of the Complaint.

55. Medtronic admits that there is no specific test to determine whether a particular lead will fail at a particular time in a particular patient and denies the remaining allegations of Paragraph 55 of the Complaint as stated. Further answering, Medtronic refers to the full content of its October 15, 2007 communication (and appendices) to physicians and denies any allegations contained in Paragraph 55 that vary from the statements contained in that communication and denies any remaining allegations of Paragraph 55.

56. Medtronic denies the allegations of Paragraph 56 of the Complaint as stated. Further answering, Medtronic refers to the full content of its October 15, 2007 communication (and

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appendices) to physicians and denies any allegations contained in Paragraph 56 that vary from the statements contained in that communication and denies any remaining allegations of Paragraph 56.

57. Paragraph 57 states a legal conclusion to which no response is required. To the extent a response is required, Medtronic denies the allegations of Paragraph 57 of the Complaint.

58. Medtronic is without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 58 relating to Plaintiff Baque and purported class members. Medtronic denies the existence of any defect or any characterization of its leads as fragile, as well as the remaining allegations of Paragraph 58 of the Complaint.

59. Paragraph 59 states a legal conclusion to which no response is required. To the extent a response is required, Medtronic denies the allegations of Paragraph 59 of the Complaint.

60. Paragraph 60 states a legal conclusion to which no response is required. To the extent a response is required, Medtronic denies the allegations of Paragraph 60 of the Complaint.

61. Medtronic admits that its devices provide life-saving therapy to thousands of patients. Except as thus stated, Medtronic is without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 61 of the Complaint.

62. Medtronic is without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 62 of the Complaint.

63. Paragraph 63 states a legal conclusion to which no response is required. To the extent a response is required, Medtronic denies the allegations of Paragraph 63 of the Complaint.

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64. Medtronic admits that it or one of its affiliates was engaged in the business of researching, designing, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging, and/or advertising for sale, and selling certain products. The remaining allegations of Paragraph 64 state a legal conclusion to which no response is required. To the extent a response is required, Medtronic denies the remaining allegations of Paragraph 64 of the Complaint. Further answering, Medtronic is without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 64 relating to Plaintiff Baque and purported class members.

65. Paragraph 65 states a legal conclusion to which no response is required. To the extent a response is required, Medtronic denies the allegations of Paragraph 65 of the Complaint.

PLAINTIFF

66. Medtronic is without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 66, except that it acknowledges that it or one of its affiliates manufactures the model number 6949 Sprint Fidelis lead.

67. Medtronic is without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 67. However, Medtronic specifically denies that it manufactured a defective product and that its actions or products caused any injury to Plaintiff.

68. Medtronic is without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 68 as to Plaintiff Baque. Medtronic denies the remaining allegations of Paragraph 68 of the Complaint.

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CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF

(Products Liability)

69. Medtronic repeats and reasserts the responses to the allegations above as if fully set forth herein.

70. Medtronic admits that it, or one of its affiliates, designed, manufactured, assembled, promoted, advertised, sold and distributed Sprint Fidelis leads, but is without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 70.

71. Medtronic is without knowledge or information sufficient to form a belief as to the truth of the allegations in the first sentence of Paragraph 71. Medtronic denies the remaining allegations of Paragraph 71 of the Complaint.

72. Medtronic denies the allegations of Paragraph 72 of the Complaint.

73. Medtronic is without knowledge or information sufficient to form a belief as to the truth of the allegations in the first sentence of Paragraph 73. Medtronic denies the remaining allegations of Paragraph 73 of the Complaint.

74. Medtronic is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 74 as they relate to Plaintiff or unknown putative class members. Medtronic denies the remaining allegations of Paragraph 74 of the Complaint.

75. Paragraph 75 states a legal conclusion to which no response is required. To the extent a response is required, Medtronic denies the allegations of Paragraph 75 of the Complaint.

76. Paragraph 76 states a legal conclusion to which no response is required. To the extent a response is required, Medtronic denies the allegations of Paragraph 76 of the Complaint.

SECOND CLAIM FOR RELIEF

(Breach of Implied Warranty)

77. Medtronic repeats and reasserts the responses to the allegations above as if fully set forth herein.

78. Medtronic denies the allegations of Paragraph 78 of the Complaint.

79. Medtronic denies the allegations of Paragraph 79 of the Complaint.

80. Paragraph 80 states a legal conclusion to which no response is required. To the extent a response is required, Medtronic denies the allegations of Paragraph 80 of the Complaint.

81. Paragraph 81 states a legal conclusion to which no response is required. To the extent a response is required, Medtronic denies the allegations of Paragraph 81 of the Complaint.

THIRD CLAIM FOR RELIEF

(Negligence)

82. Medtronic repeats and reasserts the responses to the allegations above as if fully set forth herein.

83. Paragraph 83 states a legal conclusion to which no response is required. To the extent a response is required, Medtronic denies the allegations of Paragraph 83 of the Complaint.

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84. Paragraph 84 states a legal conclusion to which no response is required. To the extent a response is required, Medtronic denies the allegations of Paragraph 84 of the Complaint.

85. Paragraph 85 states a legal conclusion to which no response is required. To the extent a response is required, Medtronic denies the allegations of Paragraph 85 of the Complaint.

86. Paragraph 86 states a legal conclusion to which no response is required. To the extent a response is required, Medtronic denies the allegations of Paragraph 86 of the Complaint.

87. Paragraph 87 states a legal conclusion to which no response is required. To the extent a response is required, Medtronic denies the allegations of Paragraph 87 of the Complaint.

FOURTH CLAIM FOR RELIEF

(Intentional Infliction of Emotional Distress)

88. Medtronic repeats and reasserts the responses to the allegations above as if fully set forth herein.

89. Paragraph 89 states a legal conclusion to which no response is required. To the extent a response is required, Medtronic denies the allegations of Paragraph 89 of the Complaint.

90. Medtronic denies the allegations of Paragraph 90 of the Complaint.

91. Medtronic denies the allegations of Paragraph 91 of the Complaint.

92. Paragraph 92 states a legal conclusion to which no response is required. To the extent a response is required, Medtronic denies the allegations of Paragraph 92 of the Complaint.

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93. Paragraph 93 states a legal conclusion to which no response is required. To the extent a response is required, Medtronic denies the allegations of Paragraph 93 of the Complaint.

FIFTH CLAIM FOR RELIEF

(Negligent Infliction of Emotional Distress)

94. Medtronic repeats and reasserts the responses to the allegations above as if fully set forth herein.

95. Paragraph 95 states a legal conclusion to which no response is required. To the extent a response is required, Medtronic denies the allegations of Paragraph 95 of the Complaint.

96. Paragraph 96 states a legal conclusion to which no response is required. To the extent a response is required, Medtronic denies the allegations of Paragraph 96 of the Complaint.

97. Paragraph 97 states a legal conclusion to which no response is required. To the extent a response is required, Medtronic denies the allegations of Paragraph 97 of the Complaint.

SIXTH CLAIM FOR RELIEF

(Violation of Consumer Protection Statutes)

98. Medtronic repeats and reasserts the responses to the allegations above as if fully set forth herein.

99. Paragraph 99 states a legal conclusion to which no response is required. To the extent a response is required, Medtronic denies the allegations of Paragraph 99 of the Complaint.

100. Medtronic denies the allegations of Paragraph 100 of the Complaint.

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101. Paragraph 101 states a legal conclusion to which no response is required. To the extent a response is required, Medtronic denies the allegations of Paragraph 101 of the Complaint.

102. Paragraph 102 states a legal conclusion to which no response is required. To the extent a response is required, Medtronic denies the allegations of Paragraph 102 of the Complaint.

103. Paragraph 103 states legal conclusions to which no response is required. To the extent a response is required, Medtronic denies the allegations of Paragraph 103 of the Complaint.

104. Paragraph 104 states a legal conclusion to which no response is required. To the extent a response is required, Medtronic denies the allegations of Paragraph 104 of the Complaint.

105. Medtronic denies the allegations of Paragraph 105 of the Complaint.

106. Paragraph 106 states a legal conclusion to which no response is required. To the extent a response is required, Medtronic denies the allegations of Paragraph 106 of the Complaint.

107. Paragraph 107 states a legal conclusion to which no response is required. To the extent a response is required, Medtronic denies the allegations of Paragraph 107 of the Complaint.

108. Paragraph 108 states a legal conclusion to which no response is required. To the extent a response is required, Medtronic denies the allegations of Paragraph 108 of the Complaint.

109. Paragraph 109 states a legal conclusion to which no response is required. To the extent a response is required, Medtronic denies the allegations of Paragraph 109 of the Complaint.

110. Paragraph 110 states a legal conclusion to which no response is required. To the extent a response is required, Medtronic denies the allegations of Paragraph 110 of the Complaint.

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111. Paragraph 111 states a legal conclusion to which no response is required. To the extent a response is required, Medtronic denies the allegations of Paragraph 111 of the Complaint.

112. Paragraph 112 states a legal conclusion to which no response is required. To the extent a response is required, Medtronic denies the allegations of Paragraph 112 of the Complaint.

SEVENTH CLAIM FOR RELIEF

(Breach of Express Warranties)

113. Medtronic repeats and reasserts the responses to the allegations above as if fully set forth herein.

114. To the extent that the allegations of Paragraph 114 rely upon public documents, the documents speak for themselves and Medtronic refers to them for the full content of such documents. To the extent that such allegations vary from any of the statements contained in the public documents, Medtronic denies those allegations. Medtronic denies any remaining allegations of Paragraph 114 of the Complaint.

115. Paragraph 115 states a legal conclusion to which no response is required. To the extent a response is required, Medtronic denies the allegations of Paragraph 115 of the Complaint.

116. Paragraph 116 states a legal conclusion to which no response is required. To the extent a response is required, Medtronic denies the allegations of Paragraph 116 of the Complaint.

117. Paragraph 117 states a legal conclusion to which no response is required. To the extent a response is required, Medtronic denies the allegations of Paragraph 117 of the Complaint.

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118. Paragraph 118 states a legal conclusion to which no response is required. To the extent a response is required, Medtronic denies the allegations of Paragraph 118 of the Complaint.

EIGHTH CLAIM FOR RELIEF

(Unjust Enrichment)

119. Medtronic repeats and reasserts the responses to the allegations above as if fully set forth herein.

120. Paragraph 120 states a legal conclusion to which no response is required. To the extent a response is required, Medtronic denies the allegations of Paragraph 120 of the Complaint.

121. Paragraph 120 states a legal conclusion to which no response is required. To the extent a response is required, Medtronic denies the allegations of Paragraph 120 of the Complaint.

122. Paragraph 122 states a legal conclusion to which no response is required. To the extent a response is required, Medtronic denies the allegations of Paragraph 122 of the Complaint.

NINTH CLAIM FOR RELIEF

(Declaratory Relief and Medical Monitoring)

123. Medtronic repeats and reasserts the responses to the allegations above as if fully set forth herein.

124. Paragraph 124 states a legal conclusion to which no response is required. To the extent a response is required, Medtronic denies the allegations of Paragraph 124 of the Complaint.

125. Medtronic denies the allegations of Paragraph 125 of the Complaint.

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126. Medtronic denies the allegations of Paragraph 126 of the Complaint, except to the extent that Medtronic admits that any surgery or procedure to remove an implanted lead exposes the patient to risks of such surgery or procedure and potential complications following surgery or a procedure.

127. Medtronic is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 127.

128. To the extent that Paragraph 128 purports to be a legal argument or a specific request for relief or states a legal conclusion, no response is required. To the extent a response is required, Medtronic denies the allegations of Paragraph 128 of the Complaint and denies that Plaintiff or any putative class are entitled to the requested relief.

PRAYER FOR RELIEF

Medtronic denies that it is liable to Plaintiff or any putative class in any manner whatsoever. Medtronic further denies that Plaintiff or any putative class is entitled to any of the relief requested in his prayer for relief.

GENERAL DENIAL

All allegations not specifically admitted herein are hereby denied.

AFFIRMATIVE DEFENSES

Medtronic, while reserving the right to assert other defenses as discovery proceeds, and without assuming the burden of proof when the burden of proof rests on Plaintiff, asserts the following separate and independent affirmative defenses in further opposition to the Complaint:

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1. Plaintiff's Complaint, and each count and claim contained therein, fails to state a claim upon which relief can be granted.

2. Plaintiff's claims are barred, in whole or in part, by the applicable statutes of limitation and/or the doctrine of laches.

3. Plaintiff's claims are barred, in whole or in part, by the doctrines of estoppel, unclean hands and waiver.

4. Plaintiff's claims are barred, in whole or in part, by the doctrines of res judicata, collateral estoppel, issue preclusion and/or claim preclusion.

5. Plaintiff's claims are barred, in whole or in part, because the Food and Drug Administration has exclusive or primary jurisdiction over the matters asserted in the Complaint.

6. Plaintiff's claims are preempted, in whole or in part, by federal laws and regulations, including without limitation those governing the labeling, advertisement and sale of medical devices.

7. Plaintiff's claims are preempted, in whole or in part, by the deference the common law gives to discretionary actions by the Food and Drug Administration under the Food, Drug and Cosmetic Act, and the Medical Device Amendments thereto.

8. Plaintiff's claims are barred, in whole or in part, because there is no private right of action under the Food, Drug and Cosmetic Act for claims such as those asserted by Plaintiff.

9. Plaintiff's claims are barred, in whole or in part, because at all times relevant to the Complaint, Medtronic met or exceeded the requisite standard of care.

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10. Plaintiff's claims are barred, in whole or in part, because Medtronic did not owe any duty to Plaintiff.

11. Plaintiff's claims are barred, in whole or in part, because no act or omission on Medtronic's part caused or contributed to the alleged injuries and damages described in the Complaint.

12. Plaintiff's claims are barred, in whole or in part, because Plaintiff's alleged injuries, if any, were the result of intervening and/or superseding causes.

13. Plaintiff's claims are barred, in whole or in part, by Plaintiff's comparative or contributory fault or negligence.

14. Plaintiff's claims are barred, in whole or in part, because no action or inaction by Medtronic was the proximate cause of Plaintiff's alleged damages, if any.

15. Plaintiff's claims are barred, in whole or in part, because Plaintiff's alleged damages, if any, were caused in whole or in part by the acts or omissions of Plaintiff or third parties over whom Medtronic had no control or authority.

16. Plaintiff's claims are barred, in whole or in part, because Plaintiff assumed the risk of his alleged injuries, if any, and engaged in the activities alleged in the Complaint after giving his informed consent.

17. Plaintiff's claims are barred, in whole or in part, by the learned intermediary doctrine, because Medtronic provided adequate warnings to learned intermediaries.

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18. Plaintiff's claims are barred, in whole or in part, because any alleged injuries or damages sustained by Plaintiff may have been caused by the misuse or abuse of Medtronic's products by Plaintiff or other persons.

19. Plaintiff's claims are barred, in whole or in part, because Medtronic's products may have been substantially changed after they left Medtronic's control and before Plaintiff suffered any alleged injuries or damages.

20. Plaintiff's claims are barred, in whole or in part, because any alleged injuries or damages sustained by Plaintiff may have been caused by the alteration and/or method of implantation and/or maintenance of Medtronic's products after they left Medtronic's control.

21. Plaintiff's claims are barred, in whole or in part, because any alleged injuries or damages sustained by Plaintiff may have been the direct result of Plaintiff's pre-existing medical conditions, sub-medical conditions, natural causes, or the result of other circumstances over which Medtronic had no control and for which Medtronic is not responsible.

22. Plaintiff's claims are barred, in whole or in part, because any alleged injuries or damages sustained by Plaintiff may be the result of an unforeseeable series of events over which Medtronic had no control, and as such, constitutes acts of God for which Medtronic cannot be held liable.

23. Plaintiff's claims are barred, in whole or in part, because any alleged injuries or damages sustained by Plaintiff may be the result of idiosyncratic reactions by Plaintiff that were not reasonably foreseeable and for which Medtronic cannot be held liable.

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24. Plaintiff's claims are barred, in whole or in part, because the risks associated with the use of the medical devices at issue, if any, are outweighed by the utility and benefits such devices provide.

25. Plaintiff's claims are barred, in whole or in part, because the medical device at issue was not unreasonably dangerous or defective, was suitable for the purpose for which it was intended, and was distributed with adequate and sufficient warnings.

26. Plaintiff's claims are barred, in whole or in part, because the methods, standards and techniques of designing, manufacturing and labeling the medical devices at issue complied with and conformed to the generally recognized state of the art at the time such devices were designed, manufactured and labeled.

27. Plaintiff's claims are barred, in whole or in part, because Plaintiff fails to assert a feasible safer design for Medtronic's products alleged to be defective.

28. Plaintiff's claims are barred, in whole or in part, because Medtronic acted reasonably and in good faith at all times material herein, based on all relevant facts and circumstances known by Medtronic at the time it acted.

29. Plaintiff's claims are barred, in whole or in part, because Plaintiff did not rely reasonably on any act, omission or representation made by Medtronic.

30. Plaintiff's claims are barred, in whole or in part, because there was no defect in the device at issue at the time it left Medtronic's possession.

31. Plaintiff's claims are barred, in whole or in part, because to the extent Plaintiff alleges that Medtronic failed to warn about alleged defects in the device at issue or other alleged causes of

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Plaintiff's injuries or damages, if any, the doctors and other health care providers associated with the device were or should have been aware of any risks or hazards associated with it, and to the extent that such doctors and health care providers failed to advise, inform or warn Plaintiff of such risks or hazards, Medtronic cannot be held responsible.

32. Plaintiff's claims are barred, in whole or in part, to the extent that he has failed to plead actual injury.

33. Plaintiff's claims are barred, in whole or in part, to the extent that the alleged injuries are too remote from Medtronic's conduct to state a claim.

34. Plaintiff's claims are barred, in whole or in part, by the economic loss doctrine.

35. Medtronic adopts and incorporates by reference as if fully set out herein any and all defenses which are or may become available to it under the Restatement (Second) of Torts § 402A and all comments thereto, and the Restatement (Third) of Torts §§ 1-21 and comments thereto.

36. Plaintiff's claims are barred, in whole or in part, by the principles set forth in the Restatement (Second) of Torts § 388, Comment n, and any similar doctrines and/or principle in the Restatement (Third) of Torts.

37. Plaintiff's claims are barred, in whole or in part, by the principles set forth in the Restatement (Second) of Torts § 402A, Comment k, and the Restatement (Third) of Torts: Products Liability § 6.

38. Plaintiff's claims are barred, in whole or in part, because to the extent Plaintiff alleges failure to warn by Medtronic, the doctors and other health care providers who were associated with the device at issue, or were or should have been aware of any risk and/or hazard that Plaintiff alleges

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rendered the device defective and allegedly caused Plaintiff's damages, if any, failed to warn Plaintiff of such risks and/or hazards.

39. Plaintiff's warranty-based claims are barred, in whole or in part, because Medtronic did not make or breach any warranties that are applicable to Plaintiff.

40. Plaintiff's warranty-based claims are barred, in whole or in part, by Plaintiff's failure to give proper or timely notice of any alleged defect or breach of warranty.

41. Plaintiff's warranty-based claims are barred, in whole or in part, because Plaintiff was not in privity with Medtronic.

42. Plaintiff's warranty-based claims are barred, in whole or in part, by any and all express conditions, disclaimers, modifications or exclusions made by Medtronic.

43. Plaintiff's warranty-based claims are barred, in whole or in part, by Plaintiff's lack of reliance on any such warranties.

44. Plaintiff's warranty-based claims are barred, in whole or in part, by Plaintiff's failure to satisfy all conditions precedent or subsequent to the enforcement of any such alleged warranties.

45. Plaintiff's claims are barred, in whole or in part, because the promotion of products sold or manufactured by Medtronic is protected by the First Amendment of the United States Constitution and similar provisions in applicable state constitutions.

46. Plaintiff's claims are barred, in whole or in part, to the extent that they lack standing to pursue the claims alleged against Medtronic.

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47. Plaintiff's claims are barred, in whole or in part, because Medtronic did not violate any statute or law, as alleged by Plaintiff.

48. To the extent Plaintiff is required to plead his claims with sufficient particularity to satisfy the requirements of Federal Rule of Civil Procedure 9, he has failed to do so and his claims must be dismissed.

49. Plaintiff's claims under state consumer fraud and unlawful or deceptive trade practice acts are barred to the extent that Plaintiff has not alleged any misrepresentation or misleading statement with the specificity required by Federal Rule of Civil Procedure 9(b).

50. The Complaint does not allege a class properly certifiable under Federal Rule of Civil Procedure 23 because and to the extent that Plaintiff is not an adequate class representative, the claims are not typical of those of the purported class, common issues do not predominate, and a class action would be unmanageable and not superior to other methods of adjudicating the claims of Plaintiff and the classes he purports to represent.

51. Plaintiff's claims are barred, in whole or in part, because Medtronic is entitled to the benefit of all defenses and presumptions contained in, or arising from, any rule of law or statute of any state whose substantive law controls the action.

Illustratively, Plaintiff's claims under the consumer protection statutes of each individual state are barred because Medtronic does not fit within the statutory definitions of the type of defendant contemplated by these statutes, Plaintiff does not fit within the statutory definitions of the proper type of plaintiff contemplated by these statutes, and Plaintiff's claimed injuries do not fit within the statutory definitions of actionable injuries contemplated by these statutes.

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52. Plaintiff's claims are barred, reduced and/or limited pursuant to applicable statutory and common law regarding limitation of awards, caps on recovery and setoffs.

53. Any verdict or judgment that might be recovered by Plaintiff must be reduced by those amounts that have already indemnified Plaintiff, or will in the future with reasonable certainty indemnify Plaintiff, in whole or in part, for any past or future claimed economic loss, from any collateral source including but not limited to insurance, social security, workers' compensation or employee benefit programs.

54. In the event that Plaintiff has sustained damages as alleged in the Complaint, which Medtronic denies, discovery or investigation may reveal that Plaintiff's claims are barred or reduced to the extent Plaintiff failed to mitigate any damages allegedly sustained.

55. Plaintiff's claims for punitive or exemplary damages are barred or reduced by applicable law or statute, or in the alternative, are unconstitutional insofar as they violate the due process protections afforded by the United States Constitution, the excessive fines clause of the Eighth Amendment to the United States Constitution, and any other applicable provisions of the United States Constitution or any applicable state constitution. Any law, statute or other authority purporting to permit the recovery of punitive or exemplary damages in this case is unconstitutional, facially and/or as applied to Medtronic.

56. Plaintiff's claims for punitive or exemplary damages are barred, in whole or in part, because such damages are not recoverable for the causes of action set forth in the Complaint, or in the alternative, the allegations of each cause of action in the Complaint are legally insufficient to support a claim for punitive or exemplary damages.

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57. Plaintiff's claims for punitive or exemplary damages are barred, in whole or in part, because Medtronic did not act with the requisite level of conduct to be subjected to or that would otherwise support any punitive or exemplary damages in this action.

58. Plaintiff is not entitled to attorneys' fees under any act or theory forming the basis of any of Plaintiff's claims.

WHEREFORE, having fully answered and defended, Medtronic demands trial by jury on all issues so triable, and prays that the Court:

1. Dismiss Plaintiff's Complaint in its entirety with prejudice;

2. Enter judgment in favor of Defendant on all claims;

3. Award Defendant its costs incurred defending this action, including reasonable attorneys' fees; and

4. Grant Defendant such other and further relief as the Court deems just and proper.

DATED: December 13, 2007.

REED SMITH LLP

By /s/ Dana A. Blanton
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Medtronic, Inc., a corporation

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